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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,805	03/16/2007	Ronald Quinn	3573-117 US	8855

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,805	QUINN ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2,3,5 and 7-23* is/are allowed.

6)☒ Claim(s) *4,6 and 24-26* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *May 17, 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted March 3, 2008 wherein claims 1, 8, 9, 14-17 and 24 are amended. This application is a national stage application of PCT/AU04/01660, filed November 26, 2004, which claims priority to foreign application AU2003906558, filed November 27, 2003.

Claims 1-26 are pending in this application.

Election/Restrictions

Applicant's election without traverse of group I, drawn to a compound of formula(I), filed March 3, 2008, is acknowledged. However the requirement for restriction is withdrawn in view of the allowability of the base claim 1 from which claim 26 depends.

Claims 1-26 as amended are examined on the merits herein.

Claim Objections

Claim 1 is objected to because of the following informalities: The substituent R_4 is defined as CH_2OO-alkyl. Although this substituent is a legitimate alkyl peroxide structure, when compared to the definition of R_4 in the specification it is unclear whether this is a typographical error as the specification (for example p. 7 line 16), recites CH_2COO-alkyl. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim 1 defines the substituents R_4 and R_6 as being particular functional groups. Dependent claim 4 defines R_4 including O-acetyl or hydroxyl which are not included in the definition of R_4 in the base claim. Dependent claim 6 defines R_6 as methyl which is not included in the limitations of the base claim. Therefore it is unclear what the limitations of these claims are as they lack antecedent basis in the base claim, rendering them indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory or nociceptive pain, does not reasonably provide enablement for a method of treating neuropathic or psychogenic pain. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a method of treating pain in a subject, comprising administering a particular pharmaceutical compound. In order to be enabled for using this invention, one skilled in the art must be able to, without undue or unpredictable experimentation, be able to use the claimed compound to treat all types of pain.

The state of the prior art: The treatment of pain is a complex art due to the fact that pain can be caused by many different disorders, and no one treatment is universally useful for the treatment of all pain. In particular, pain is divided into neuropathic, nociceptive, and psychogenic categories, representing pain arising from a disorder of the nervous system, a painful stimulus to the nerves, or a psychological stress disorder, respectively. As described by Woolf et al. (Reference included with PTO-892) drugs used to treat nociceptive pain, including non-steroidal anti-inflammatory

drugs and opiates, are often ineffective against neuropathic pain, such as that arising from nerve injury or diabetes, and vice versa. (p. 1959, left column, second paragraph) According to Woolf et al., "There is no treatment to prevent the development of neuropathic pain, nor to adequately, predictably, and specifically control established neuropathic pain." (p. 1959, left column, third paragraph)

As described by the Merck manual of Diagnosis and Therapy (Reference included with PTO-892) the appropriate treatment for psychogenic pain is primarily centered around cognitive and behavioral approaches rather than drug therapy. (p. 1374)

Inflammation is a process that occurs in damaged tissue and which produces pain or sensitized the subject to pain. Because it is the result of local injury to the affected tissue rather than to the central or peripheral nervous system, inflammation causes nociceptive pain rather than neuropathic pain. An anti-inflammatory pharmaceutical treatment will be expected to treat certain cases of nociceptive pain but not neuropathic or psychogenic pain, which are not the result of damaged or inflamed tissue.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While there exist many drugs for the treatment of pain and inflammation, there is no panacea which is capable of relieving all types of pain. Each individual drug for the treatment of pain must be evaluated on its own merits as to the specific cases in which is it or is not useful.

The Breadth of the claims: Claim 26 is drawn to methods of treating all forms of pain, including nociceptive pain such as that resulting from tissue damage of inflammation, neuropathic pain such as that resulting from nerve damage or diabetes, and psychogenic pain which is due primarily to psychological factors.

The amount of direction or guidance presented: The instant specification describes the compounds as useful for the treatment of pain. No further specifics are provided that would indicate to one skilled in the art what sorts of pain are treatable or what mechanism the compound works by. Specifically, no neurological or psychological effects are noted for the claimed compounds.

The presence or absence of working examples: The instant specification describes on pp. 45-48 experimental protocols in which rats were treated for inflammatory pain and pain resulting from hindpaw pressure. These examples involve local insult or damage to tissue and are clearly examples of nociceptive pain. The disclosed examples cannot be seen in any way to involve the treatment of neuropathic or psychogenic pain.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the treatment of neuropathic or psychogenic pain. See MPEP 2164.

The quantity of experimentation necessary: In order to treat neuropathic or psychogenic pain using the claimed saponins, a skilled practitioner of the art would undertake to develop a therapeutic regimen without precedent in the current state of the

art. As the applicant's disclosure provides no guidance for the treatment of neuropathic or psychogenic pain, the development of this therapeutic method would be an independent research endeavor which would present significant obstacles, mainly arising from the fact that neither of the drugs included in the claimed combination is known to affect any molecular target involved in neuropathic or psychogenic pain, or to have any pharmacological effect that would lead one skilled in the art to consider it as a potential treatment for these types of pain. This process would involve the screening of candidate compounds against relevant molecular targets, optimization of lead activity, and validation of lead compounds using *in vivo* animal models of neuropathic pain. Developing such a therapeutic method without guidance from applicant's disclosure represents an undue experimental burden to one skilled in the art wishing to practice the invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the utter lack of precedent in the prior art or in Applicant's disclosure for the treatment of neuropathic or psychogenic pain using the claimed compounds, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of neuropathic pain, absent undue experimentation.

Conclusion

Claims 4, 6, and 24-26 are rejected. Claim 1 is objected to for minor informalities. Claims 2, 3, 5, and 7-23 are seen to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
9/24/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623